REMARKS/ARGUMENTS

In response to the Final Office Action mailed May 20, 2011 and the Advisory Action mailed August 1, 2011, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, claim 1 is proposed to be amended, no claims have been cancelled without prejudice and no claims have been added, so that claims 1 and 6-8 are currently pending. No new matter has been entered.

Claim 1 was objected to for a number of informalities which Applicants have corrected.

Claims 1 and 6-8 were rejected under 35 USC 112, first paragraph and second paragraphs. Applicants have proposed to amend claim 1 to more clearly claim the invention. More specifically, applicants have used the data from Figure 64 which shows the concentration of rapamycin starting at about 1x10-10 or 0.1 nanomolar and rising. As can be seen from curve 6402 which is just rapamycin, there is no percent inhibition between 0.1 and 1 nanomolar concentrations. However, when a 300 nano molar amount of topotecan is added to the rapamycin in the same range, close to 100 percent inhibition is achieved.

Figure 64 illustrates the antiproliferative activity with varying concentrations of topotecan in synchronized cultural human coronary artery smooth muscle cells stimulated with two percent fluid bovine serum. These curves are generated via data points with a simple correction between the data points. These are accurate curve fits and fairly represent the data points between the points utilized to create the curve. And thus the claim clearly sets forth the invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully submitted.

Claims 1 and 6-8 were rejected as being unpatentable over US Patent Publication No. 2002/0133183 to Lentz et al. (Lentz), U.S. Patent Application No.

2002/0004679 to Eury et al. (Eury), US 2003/0065382 to Fischell et al. (Fischell) and WO 96/34003 to Shull et al. (Shull) and U.S. Patent Application No. 2002/0123505 to Mollison et al. (Mollison). This rejection is respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations. Claim 1 claims a medical device comprising an implantable structure, a basecoat matrix of just polymer and two drugs, topotecan and rapamycin, and a topcoat comprising a second polymer which is different from the first polymer and contains no drugs. The concentration of rapamycin is between 0.1 and 1 nanomolar and the concentration of topotecan is 300 nanomolar.

Lentz discloses a medical device coated with various drugs and polymers. Fischell discloses a stent coated with a number of polymers, a number of drugs, including sirolimus which is a rapamycin. The drugs may be on the surface of the polymer or mixed in with the polymer. Eury discloses a stent coated with a topoisomerase inhibitor for treating restenosis. The stent may be fabricated from a polymer loaded with topotecan plus other drugs. Shull discloses the use of various analogs of camptothecin. Mollison discloses medical devices containing rapamycin analogs.

The references taken as a whole fail to disclose or even suggest a medical device with two specific drugs in the specific dosages in a two distinct polymer

structure. None of the references disclose or suggest the nanomolar concentrations of the two drugs used together in a matrix structure that uses the different classes of polymers. The extremely low concentration of rapamycin is possible because of the synergistic effect of the topotecan. In other words topotecan clearly potentiates low dose rapamycin as can be seen from comparing curve 6402 to curve 6412. The data points fit along the smooth curve. Also, the references do not teach separate and distinct layers of polymers that are chemically and physically incompatible. In addition, assuming arguendo that the references do teach all of the claimed elements there is simply no motiviation to combine the references. As set forth in Philip W. Wyers and Wyers Products Group, Inc., v. Master Lock Company, 616F.3d 1231; 2010 U.S. App., the motivation to combine should involve a common sense evaluation. Why should the references be combined to create a multiple class polymer system with the drugs within its known that single drugs and single polymers also work. It appears that the Examiner is piecing the art together by using the claims as a template and this is impermissible. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Carl J. Evens/

By:_____
Carl J. Evens
Reg. No. 33,874

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518
Dated: August 1, 2011